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08/732,408	12/09/1996	JOHANNES REINMULLER	HUBR1099PFFM	7906

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EXAMINER	
PELLEGRINO, BRIAN E	
ART UNIT	PAPER NUMBER
3738	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	08/732,408	REINMULLER, JOHANNES	
	Examiner	Art Unit	
	Brian E. Pellegrino	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *129,134,146-167,175,176,179 and 180* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *129,134,146-167,175,176,179 and 180* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

The amendment filed 6/24/10 has been entered after a decision by the Board of Patent Appeals and Interferences to reopen to present a new grounds of rejection under 37 CFR 41.50 (b). The Examiner's position with respect to the Henley reference are presented in the Answer of 2/21/06. However, in view of the amendment to the claims the Henley is modified with other references as being obvious. In addition Applicants amendment with respect to claims 129,147,175 and prior arguments have been considered but are moot in view of the new ground(s) of rejection presented below.

Claim Objections

Claims 146,167 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Both claims depend from canceled claims.

Claim 160 is objected to because of the following informalities: in line 1 of the claim the word "material" precedes the recitation "said physiologically compatible material" which is redundant. It appears as a typo and is interpreted as such. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 129,134,146-167,175,176,179,180 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claims 129,147,175, the phrase "strand-like" renders the claim(s) indefinite because the claim(s) fail to define specifically what structure is being claimed (those encompassed by "strand-like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d). The specification fails to define what the difference is between a “silicone rubber element” and a “strand-like silicone rubber element” since no specific definition was provided to explain what an "element” is structurally configured as. Applicant provides characteristics of the "silicone rubber elements” such as being thin, pages 4,5 of specification. Does this mean then that all silicone rubber elements that are considered “thin” can define “strand-like”? Thin can be used to define relative dimensions, but it does not impart any particular structure to further limit an element. Without any specific feature being clearly defined by the claims, the metes and bounds of the claims cannot be determined and are therefore indefinite. Claims 134,146,148-167,176,179,180 are also indefinite for depending from indefinite claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 129,146-153,155,167,175,176,179,180 are rejected under 35 U.S.C. 102(b) as being anticipated by Giampapa (5137533). Fig. 1 shows a “strand-like” element **14**. Giampapa discloses the "strand-like” elements comprise silicone rubber that is physiologically compatible, col. 2, lines 2,3,7,46,51,52. With respect to claims 146-148 Fig. 4 shows surfaces of the “strand-like" elements **17** are surrounded by a covering material **16** which is hydrophilic or wettable, col. 2, lines 55,56,61,62. Regarding claim 149, the wettable surface **16** comprises silicon rubber core **12** within it, Fig. 2, col. 2, lines 38-40. With respect to claims 150,151 Giampapa disclose the outer surface is hyrophilized and an aqueous lubricant can contact it, col. 2, lines 59-62. Regarding claims 152,153,164 Giampapa further discloses that the fluid lubricant swells the surface and can be construed as a foam structure, col. 2, lines 62-65. With respect to claim 155, Giampapa discloses the strand elements are coated with hydrophobic silicone such that it prevents body reactions, col. 3, lines 38-43. Note that Lai (5486579) disclose that silicone is known to be hydrophobic. Regarding claim 167, it can be seen

(Figs. 1-6) that there is a plurality of element strands. Regarding claims 175,176, 179,180 Giampapa discloses that the implant is to be inserted into a site of subject, col. 2, lines 3,24,25,27,63,64. Please note that functional limitations must be supported by sufficient structure in the claim for the function to occur in order to be afforded patentable weight.

Claims 129,134,167,175,176 are rejected under 35 U.S.C. 102(b) as being anticipated by Pinchuk et al. (5116360). Fig. 2 shows a medical implant **41** comprising a plurality of strand-like rubber elements of silicone, col. 5, lines 25-27, col. 6, lines 36-39. With respect to claim 134, Pinchuk discloses a material for wetting the surface, col. 4, lines 19-22. Regarding claims 175, 176, Pinchuk et al. disclose to implant the device, col. 7, lines 19-21.

Claims 129,134, 175,176, are rejected under 35 U.S.C. 102(e) as being anticipated by Henley (5534023). Fig. 1 shows a medical implant with a plurality of connected strands of material **14** and an outer covering **11**. Henley discloses the covering is a silicone rubber, col. 4, lines 8-9. Henley also discloses the beads inside the covering have extrudate chains **14** in string form (col. 4, lines 29-31) that the Examiner is interpreting as “strand-like” elements since they possess a body of material having a length greater than its width. The strand of elements **14** are made of silicone, col. 4, lines 30-33. Regarding claims 175,176, Henley discloses the method of using the implant for implantation and it is placed at a soft tissue site, col. 3, lines 60-65, col. 4, lines 30. Please note that functional limitations must be supported by sufficient structure in the claim for the function to occur in order to be afforded patentable weight.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 146-155,158-160,162,179,180 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchuk et al. '360 in view of Kudo et al. (4331697). Pinchuk et al. is explained supra. A) Claim 146 is addressed first---However, Pinchuk et al. does not explicitly state the outer surface of the rubber elements are hydrophilized. Kudo et al. teach that hydrophilization is used on implant surfaces to make hydrophobic polymers more biocompatible, col. 6, lines 38,39,57-68. It would have been obvious to one of ordinary skill in the art to use a hydrophilized surface as taught by Kudo et al. with the implant of Pinchuk et al. such that it provides an antithrombic surface.

B) Regarding claims 147-153 Pinchuk discloses an outer covering **61** but does not explicitly state the surface is wettable by a fluid lubricant. Kudo et al. discloses to use lubricants such as swelling agents (col. 8) to alter the surface characteristics and hydrophilize the surface (col. 6) to bond surface materials to improve its biocompatibility with bioactive agents, such as heparin. It would have been obvious to one of ordinary skill in the art to use fluid lubricants and hydrophilize the surface as taught by Kudo et al. with the medical implant of Pinchuk et al. such that it is more compatible in the patient. Regarding claims 149, 160 Kudo further teaches that the surface that is wettable can be silicone, col. 5, lines 38-52. Thus, it would have been

obvious to have the outer covering comprise silicone. With respect to claims 154,162 Kudo teaches the polysaccharide heparin is used as a fluid lubricant to prevent thrombosis, col. 6, lines 59-62. Regarding claims 158,159 Pinchuk discloses a plastic for the outer covering, col. 2, lines 59-68. With respect to claims 179,180, see explanation above of Pinchuk regarding claims 175,176.

Claims 147-155,158-160,167, 179,180 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henley '023 in view of Lai et al. (5486579). Henley is explained supra. However, Henley does not disclose the outer covering of the implant has a wettable surface or hydrophilized surface. Lai et al. teach that silicone materials for implants are made wettable such that they make the implant more compatible with the body, col. 7, lines 10-41. Lai also teaches that the wetting agents incorporated into the polymer make the polymer hydrophilized and suitable for biological use, col. 4, lines 14-16,19-23. It would have been obvious to one of ordinary skill in the art to use wettable surfaces for the implant as taught by Lai et al. with the implant of Henley such that it is readily accepted in the patient. With respect to claims 134,152-154, Henley discloses lubricants to reduce friction can also be added, such as swellable ones or a polysaccharide such as dextran, col. 6, lines 22-26. Regarding claim 158, Henley discloses the outer covering is a silicone elastomer which can be considered plastic because Brauman (4963150) states it is known that elastomeric materials are plastic, col. 2, lines 66-68. Regarding claims 179,180 see above for explanation of claims 175,176.

Claims 156,157 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henley '023 in view of Lai et al. '579 as applied to claim 155 above, and further in view of Perry et al. (5282857). Henley as modified with Lai is explained supra. However, Henley in view of Lai do not disclose using fat or oil as a lubricant. Perry et al. teach that fats or oils in the form of glycerides are used in implants, col. 3, lines 1-4. It would have been obvious to one of ordinary skill in the art to use a fat or oil that wets a surface of the implant for lubrication as taught by Perry with the implant of Henley as modified with Lai in order to reduce friction and permit a more natural movement within a patient.

Claims 156,157 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchuk et al. '360 in view of Kudo et al. '697 as applied to claim 155 above, and further in view of Perry et al. '857. Pinchuk et al. as modified with Kudo is explained supra. However, Pinchuk et al. in view of Kudo et al. do not disclose using fat or oil as a lubricant. Perry et al. teach that fats or oils in the form of glycerides are used in implants, col. 3, lines 1-4. It would have been obvious to one of ordinary skill in the art to use a fat or oil that wets a surface of the implant for lubrication as taught by Perry with the implant of Pinchuk et al. as modified with Kudo et al. in order to reduce friction and provide a more lubricious surface to deliver through a vessel when inserting.

Claim 161 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchuk et al. '360 in view of Kudo et al. '697 as applied to claim 147 above, and further in view of Kira (4623347). Pinchuk et al. as modified with Kudo is explained supra. However, Pinchuk et al. in view of Kudo et al. do not disclose polydimethylsiloxane as the covering material. Kira teaches that the silicone polymer or

polydimethylsiloxane is used as an implant surface because of its biocompatibility and , its antithrombogenic property, col. 2, lines 51-53, 58, col. 3 lines 1-6. It would have been obvious to one of ordinary skill in the art to use polydimethylsiloxane as the covering material as taught by Kira in the vascular implant of Pinchuk et al. as modified with Kudo et al. in order to prevent thrombosis.

Claims 161,162 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henley '023 in view of Lai et al. '579 as applied to claim 147 above, and further in view of Taylor (4657553). Henley as modified with Lai is explained supra. However, Henley in view of Lai do not disclose the use of polysaccharides or polydimethylsiloxane as the implant material. Taylor teaches that polysaccharides are used in soft tissue implants and can be hydrophilic, col. 1, lines 55-57. Taylor also teaches that polydimethylsiloxane is used in constructing medical implant material, col. 4, lines 37-44. It would have been obvious to one of ordinary skill in the art to use a polysaccharide or polydimethylsiloxane as the implant material as taught by Taylor for the implant of Henley as modified with Lai because of the suitability of these materials in medical uses.

Claim 163 is rejected under 35 U.S.C. 103(a) as being unpatentable over Henley '023 in view of Lai et al. '579 as applied to claim 158 above, and further in view of Chapman (4348329). Henley as modified with Lai is explained supra. However, Henley in view of Lai do not disclose cuprophane as the plastic covering material. Chapman teaches that polymers or "plastic" used in implants have coatings that are

biocompatible, col. 6, lines 32-36,49-54 and cuprophane is one material used (col. 13, lines 9,12). It would have been obvious to one of ordinary skill in the art to use cuprophane as the plastic covering material as taught by Chapman in the implant of Henley as modified with Lai in order to reduce cell membrane damage.

Claim 163 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchuk et al. '360 in view of Kudo et al. '697 as applied to claim 158 above, and further in view of Chapman '329. Pinchuk et al. as modified with Kudo is explained supra. However, Pinchuk et al. in view of Kudo et al. do not disclose cuprophane as the plastic covering material. Chapman teaches that polymers or "plastic" used in implants have coatings that are biocompatible, especially in blood contacting surfaces, col. 6, lines 32-36,49-54 and cuprophane is one material used (col. 13, lines 9,12). It would have been obvious to one of ordinary skill in the art to use cuprophane as the plastic covering material as taught by Chapman in the vascular blood contacting implant of Pinchuk et al. as modified with Kudo et al. in order to reduce cell membrane damage.

Claims 164-166 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henley '023 in view of Lai et al. '579 as applied to claims 147,149 above, and further in view of Ledergerber (EP 322194). Henley as modified with Lai is explained supra. However, Henley in view of Lai do not disclose a foam structure in the implant or X-ray medium incorporated in the implant. Ledergerber teaches that foam can be used in the implant, col. 4, lines 8-18. Ledergerber additionally teaches that an x-ray contrast medium can be incorporated into the material, col. 12, lines 53-58. It would have been

obvious to one of ordinary skill in the art to use a foam structure or a contrast medium in the implant as taught by Ledergerber with the implant of Henley as modified with Lai such that it may be less dense as a result of using foam so it does not feel too heavy for the patient and is easily detected by imaging.

Claim 164 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchuk et al. '360 in view of Kudo et al. '697 as applied to claim 147 above, and further in view of Robinson (4731073). Pinchuk et al. as modified with Kudo is explained supra. However, Pinchuk et al. in view of Kudo et al. do not explicitly disclose the compatible material of the covering is a foam structure. Robinson teaches (Fig. 1) a foam structure for the implant surface for attachment to tissue, col. 1, lines 51,52, col. 4, lines 35-48. It would have been obvious to one of ordinary skill in the art to use a foam structure for the covering layer in the implant as taught by Robinson for the implant of Pinchuk et al. as modified with Kudo et al. such that it ensures the implant becomes affixed to tissue at the site of implantation.

Claims 165-166 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchuk et al. '360 in view of Kudo et al. '697 as applied to claims 147,149 above, and further in view of Herweck et al. (5320100). Pinchuk et al. as modified with Kudo is explained supra. However, Pinchuk et al. in view of Kudo et al. do not disclose X-ray medium incorporated in the implant. Herweck et al. teaches an x-ray contrast medium can be incorporated into the material of the implant, col. 6, lines 6-16,53-55,59-68. It would have been obvious to one of ordinary skill in the art to use a contrast medium in

the implant as taught by Herweck et al. with the implant of Pinchuk et al. as modified with Kudo et al. such that it enables the doctor, surgeon or radiologist to more easily deliver the implant and also determine if migration occurs after the implant has been implanted.

Claim 162 is rejected under 35 U.S.C. 103(a) as being unpatentable over Giampapa '533 in view of Taylor (4657553). Giampapa is explained supra. However, Giampapa does not disclose the use of polysaccharides as the implant cover material. Taylor teaches that polysaccharides are used in soft tissue implants and can be hydrophilic, col. 1, lines 55-57. It would have been obvious to one of ordinary skill in the art to use a polysaccharide as an alternative cover for implant material as taught by Taylor with the implant of Giampapa because of the suitability of this natural biological material in medical uses.

Claims 165,166 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giampapa '533 in view of Laghi (5133754). Giampapa is explained supra. However, Giampapa does not disclose the physiologically compatible material of the covering includes an X-ray contrast medium. Laghi teaches that silicone material can include an X-ray contrast medium for imaging purposes for the surgeon or doctor to inspect, col. 3, lines 8-12. It would have been obvious to one of ordinary skill in the art to use an X-ray medium in the covering as taught by Laghi such that the implant of Giampapa can be examined for proper placement in the patient.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (9am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738